

Title: School Nurse-directed Secondary Obesity Prevention for Elementary School Children  
NCT#: 02029976  
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## **Study Design Overview**

The study is a randomized controlled trial with random assignment of 8- to 12-year old children and a parent to the school nurse-delivered healthy weight management program (intervention condition) or a newsletter program (attention control condition). Cohorts of children attending schools in one of two school districts located in the St. Paul/Minneapolis, Minnesota metropolitan area, along with their parent were recruited annually for four consecutive years from 2014 to 2017. Every year, following baseline measurement conducted from June to August, child/parent dyads within each cohort were randomized to a study condition, with post intervention and follow up measurement scheduled 12- and 24-months post randomization. Delivery of the intervention and attention control condition occurred during the 9-month school year, from September to May.

## **Study Aims**

The primary and secondary aims of the study were as follows:

**Primary Aim:** To test the efficacy of an elementary school-based, school nurse-led healthy weight management program to reduce excess weight gain among children, 8- to 12-years old with a body mass index  $\geq 75^{\text{th}}$  percentile, by increasing healthy dietary practices and physical activity levels and decreasing sedentary practices. We hypothesize that relative to the attention control condition, children receiving the intervention will have a significantly lower BMI, following implementation of the 9-month intervention, controlling for baseline values.

**Secondary Aim 1:** To examine the effects of the intervention on change in the weight-related behaviors of children. We hypothesize that the intervention will result in decreased consumption of sugar-sweetened beverages and energy-dense, low-nutrient foods, increased levels of moderate to vigorous physical activity, decreased sedentary behavior, and increased fruit and vegetable intake.

**Secondary Aim 2:** To examine the effects of the intervention on family lifestyle practices overseen by parents. We hypothesize that the effects of the intervention on family lifestyle practices overseen by parents, such as home availability of healthful foods, limits on screen time, frequency of family meals, will be more prevalent among families randomized to the intervention.

## **Study Sample**

Children eligible for study participation were 8- to 12-years old, in second, third or fourth grade at the time of recruitment and attended an elementary school in one of two school

districts that volunteered to participate in the study. One school district with a kindergarten through grade 12 enrollment of about 10,000 students is located in a suburban area, includes ten elementary schools, plus one parochial school and was a recruitment and intervention site from 2014-2017. The other school district with a kindergarten through grade 12 student enrollment of approximately 37,000 is located in an urban area, includes 43 elementary schools and was a recruitment and intervention site from 2016-2018.

Eligible children were required to have a BMI  $\geq$  75th percentile, calculated using the child's height and weight, as reported by the parent, school nurse or health care provider. Studies suggest that young children in the top quartile of the growth chart are at risk for excess weight gain during the early school years and intervention during this time may be critical to preventing excess weight gain. Other inclusion criteria were child and parent able to read, write and speak English, child living with participating parent most of the time and willingness to be randomized to the intervention or the attention control condition. Exclusion criteria included plans to move outside the school district within the next 12 months, child with food allergies, physical limitations or medical conditions that would limit the child's ability to participate in physical activity and emotional health conditions that would limit the child's ability to participate in group activities with other children. Only one child per household was allowed to participate in the study.

All adult participants were required to provide written consent for self and child for study participation. Children were required to provide written assent. To allow time for review, consent forms were mailed to the parent prior to the baseline measurement visit. The consent process was completed at the first measurement visit and before baseline data collection.

## **Randomization**

After baseline assessment, child/parent dyads within each cohort and school district site were randomized to receive the intervention or the attention control condition by the study statistician using a computer-generated randomization schedule (nQuery Advisor and nQuery Advanced v. 7 through 8.1.2.0, "Statsols" (Statistical Solutions Ltd), Cork, Ireland). School district sites were determined using the following parameters. Children attended different schools located throughout each school district, with school dismissal times assigned as early (3pm) or late (4pm) based on the districtwide busing schedule. With assistance from school district staff and considerate of school dismissal times and busing routes, centrally located school buildings were identified as school district sites where intervention delivery occurred. As a result, within each cohort and school district, there were typically two intervention groups. The one exception occurred in the suburban school district in 2016, when a uniform dismissal time for elementary schools was instituted, resulting in one intervention group.

## **Assessment and Outcome Measures**

Data collection was performed by trained research staff using standardized procedures, and occurred at baseline prior to randomization, 12 months (post intervention) and 24 months (follow up) post randomization. Two person teams conducted measurement at a centrally located school district building or the participant's home, based on parent preference. The baseline and post intervention measurement required 90 minutes; the follow-up visit at 24 months post randomization required 60 minutes.

### **Child and Parent Anthropometry**

Research staff collected child and parent height and weight using standardized procedures. BMI percentiles and BMI z-scores for child's gender and age were calculated using the 2000 Centers for Disease Control and Prevention (CDC) growth charts. The study's primary outcome measure was child age- and gender-adjusted BMI z-score. We also measured parent and child body fat percentile using a Tanita TBF-300A body composition analyzer scale. All anthropometric measures were collected at baseline, post intervention and follow-up.

### **Child Dietary Intake**

Child dietary intake was assessed with multiple 24-hour dietary recall interviews, considered the gold standard for assessing dietary intake. At baseline and post intervention, trained and certified staff conducted two phone interviews with the child (one weekday and one weekend day) using the multiple pass method. Parental assistance was permitted for clarification. Recalls were collected and interpreted using the Nutrition Data Systems for Research (NDS-R) nutrient calculation software. Additional information collected during the interview included the child's eating companions, the location of the meal and use of screens while eating.

### **Child Physical Activity**

Child physical activity was assessed at baseline and post intervention with the ActiGraph uniaxial accelerometer, validated for use in children. The ActiGraph was worn at the right hip for a 7-day period; four days of complete data were required for analyses. Counts were classified into intensity categories of sedentary, light, moderate, vigorous and moderate to vigorous physical activity (MVPA) using age appropriate count cutoffs. We also calculated number and average length of MVPA bouts. Trained research staff fit the Actigraph to the child, as per standard protocols.

### **Child Health-related Quality of Life**

Health-related quality of life (QOL) has shown an inverse association with obesity among children. We used the 23-item pediatric QOL inventory, PedsQL 4.0 to assess physical, emotional, social and school functioning. The inventory takes four minutes to complete and is reliable and valid in school-aged children. The children completed the inventory independently as part of the child survey. Parents completed the parallel parent proxy report as part of the parent survey. The inventory was collected at baseline, post intervention and follow-up

## **Psychosocial Factors**

Psychosocial factors serve as predictors and mediators of behavior change and were assessed via paper and pencil surveys administered at baseline, post intervention and follow-up and completed independently by child and parent.

## **Other Survey Items**

The parent survey also included child and parent demographic information, such as gender, race, ethnicity and birthdate of participating child and parent. Parents self-reported their education, marital and employment status, household family structure, household income, eligibility for the free and reduced lunch program and household food insecurity. Items about parent and child health problems, perceived health of parent and child, frequency of child visits to health care provider and frequency of missed work by adults in the household due to child illness were assessed. The child completed a 5-item pubertal development scale shown to be reliable when compared to interviewer and physician ratings.

Parents self-reported their dietary, physical activity and sedentary practices. Measures included a validated 17-item fat screener and 6-item fruit and vegetable screener, as well as single items to assess sweetened beverage consumption, fast food restaurant use, breakfast consumption, and frequency of family meals. Parent physical activity was measured with a modified version of the Godin and Shepard Leisure Time Exercise Questionnaire; other survey items assessed weekday and weekend sedentary behaviors and parent rules related to child media use.

## **Conceptual Framework**

A social ecological framework and the healthy learner model for student chronic condition management guided intervention design, implementation and evaluation

## **Intervention Overview**

The intervention, known as SNAPSHOT (Student Nurses and Parents Seeking Healthy Options Together) was a multi-component healthy weight management program for 8- to 12-year old children that included parents and targeted key modifiable diet and activity factors known to be successful in changing long-term energy balance. Program content was consistent with the American Academy of Pediatrics obesity prevention guidelines and focuses on weight-related behaviors and lifestyle practices likely to help prevent excess weight gain in children and unlikely to cause harm. These included: 1) consume  $\geq 5$  fruit and vegetable servings/day; 2) minimize sweetened beverages; 3) decrease screen time to  $\leq 2$  hours/day; 4) limit eating out, especially fast food restaurants; 5) eat breakfast daily; 6) encourage family meals; 7) limit portion sizes; and 8) be physically active  $\geq 1$  hour/day.

The intervention was delivered by a trained registered nurse licensed as a school nurse and included (1) four, 60-minute home visits with parent and child where the school nurse provided tailored support and guidance specific to child- and parent-identified goals and priorities for weight-related behavior change; (2) 14, 90-minute 'kid' groups held during out of school time at a school district site, where children were provided guided learning, skill development and interactive play opportunities with a healthy eating and physical activity focus in a supportive group setting of similar-aged peers; and (3) five, 90-minute parent groups held early evening at a school district site that provided parents peer support, feedback and information sharing in a supportive parent-friendly setting. A full intervention dose consisted of 32.5 contact hours and two contacts with the child and one contact with the parent every month.

Child and parent dyads randomized to the attention control condition received a newsletter program consisting of monthly mailings that contained healthy lifestyle information for the family. There were also recommendations for community-based family fun events scheduled during the month with an activity focus and a healthy easy-to-make recipe.